

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

DATE: September 9, 2004

SUBJECT: Request for Human Subjects Approval (R831861), Project 2: ***Metabolic Pathways and Genes on Xenobiotic-Enhanced Allergic Inflammation***

FROM: Nigel Fields
National Center for Environmental Research (8723F)

THRU: Becki M. Clark, Director
Environmental Sciences Research Division (8723F)

TO: Roger Cortesi
National Center for Environmental Research (8701F)

04-35 #2

This memorandum requests conditional approval under Section 118 of 40 CFR 26. for the research study entitled, *Metabolic Pathways and Genes on Xenobiotic-Enhanced Allergic Inflammation*. This study is one of three proposed research projects of the Children's Environmental Health Center at the University of Southern California (R831861), all of which will involve human subjects. However this project will be conducted by researchers at the University of California, Los Angeles (UCLA) via subcontract. Materials recently submitted to the UCLA Institutional Review Board (IRB) for this project are attached.

Section 118 of 40 CFR 26 states that under certain circumstances "applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under Sec. 26.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency." A special condition will be added to this award requiring the applicant to obtain IRB approval for the study and to submit this approval to the Project Officer prior to the enrollment or use of any human subject.

IRB Number: 00004642
EPA Grant Number: R831861
Center Title: Children's Environmental Health Center
Project Title: Metabolic Pathways and Genes on Xenobiotic-Enhanced Allergic Inflammation
Institution: University of California Los Angeles
Project Investigator: David Diaz-Sanchez, Ph.D.

Attachments:

UCLA IRB Board #2 Year 1 Approval (FWA00004642)
Project 2 Year 1 consent form (approved)
Project 2 renewal consent and assent forms (recently submitted to IRB)
Project 2 narrative